

*AMENDMENT dated 08/07/2006
Application no. 10/713,177
Filed: 11/13/2003*

REMARKS

This amendment is responsive to the Office Action dated March 7, 2006. Applicant has amended claim 10. Claims 1-31 are pending.

Applicant traverses all rejections of claims in this application, and requests reconsideration in view of the arguments below.

The Examiner has rejected Claims 1-3, 24, and 27-31 under 37 U.S.C. 102(b) as being anticipated by Freeman (US 5,391,187). Claim 1 recites: "automatically determining a magnitude at which to supply the pacing stimuli, based, at least in part, upon the physical parameters ...". Claim 24 recites "a controller ... configured to... automatically determine a magnitude at which to supply the pacing stimuli, based, at least in part, upon the physical parameters". Claim 30 recites "a controller ... configured to: obtain and analyze physical parameters of the patient; automatically determine a magnitude at which to supply the pacing stimuli, based, at least in part, upon the physical parameters...". Claim 31 includes the language "automatically determining a magnitude at which to supply the pacing stimuli, based, at least in part, on whether the device previously provided a defibrillation shock to the patient, if the appropriate treatment is pacing stimuli".

Freeman does not teach any method or mechanism to determine the magnitude of pacing stimuli based on a physical parameter, or whether the device has previously provided a defibrillation shock. The Examiner recognizes that in Freeman it is "not stated explicitly that the controller determines a magnitude and a rate at which to provide pacing..." (Detailed Action, page 2, last 2 lines). Since the cited reference does not disclose all the claim limitations, these claims are not anticipated by Freeman.

Applicant takes issue with the Examiner's taking official notice that "it is well known in the art that different forms of arrhythmias are treated with different levels of voltages at different rates". Applicant respectfully submits that if this is the case, the Examiner should cite a reference demonstrating that this is so (see MPEP 2144.03). Applicant further submits that a rejection under 35 U.S.C. 102(b) cannot be based on

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a reference in combination with a taking of official notice where a claim element is not found in the reference.

Even if one assumes, solely for the sake of argument, that it is known that different forms of arrhythmias are treated with different levels of voltages at different rates, the claims still are not unpatentable under 37 U.S.C. 102(b) (or under 37 U.S.C. 103(a) for that matter) since the claim limitations directed to basing the determining of a magnitude at which to supply pacing stimuli upon a physical parameter of the patient are still not seen in the art cited by the Examiner nor in the Examiner's statement concerning treatment of different arrhythmias.

The arguments made with respect to the independent claims are applicable to the claims dependent upon them as well.

The Examiner has rejected claims 4 and 5 under 35 U.S.C. 103(a) as unpatentable over Freeman, stating that it would have been an obvious design choice to modify the defibrillator and method taught by Freeman with second and third degree atrioventricular parameters, and that "Applicant has not disclosed that the second and third degree atrioventricular parameters provide an advantage, is used for a particular purpose, or solves a state[d] problem". Applicant disagrees and takes issue with the Examiner's characterization of the claim language as being directed to an arbitrary design consideration. Furthermore, the application does disclose a particular purpose for the use of these parameters at para. 34.

The Examiner has rejected claim 6 under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Kroll (US 6,167,306). Neither Kroll nor Freeman teach that the magnitude at which to supply a pacing stimuli can be based, at least in part, upon a physical parameter which can be compared to a predetermined parameter indicating low cardiac output, as required by claim 6.

The Examiner has rejected claim 7 under 35 U.S.C. 103(a) as unpatentable over Freeman in view of Taylor (US 6,304,773). The Examiner asserts that it would have been obvious to combine the teachings of Freeman with the determination that a shock has been delivered within a predetermined time 'in order to prevent a second

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shock from being delivered and damaging the heart." (Detailed Action, page 5, para. 5, last 2 lines). Delivery of a series of three shocks to the heart of a patient in cardiac arrest has been a conventional practice, damage to the heart in VF not being an issue (see attached excerpt from Circulation, 2000 Aug 22;102(8 Suppl):I60-76: ECC Guidelines Part 4: The Automated External Defibrillator). Therefore, the Examiner's reasoning is flawed, being based on an incorrect premise.

The Examiner has rejected claims 8-17, 20, 23 and 25-26 under 35 U.S.C. 103(a) as unpatentable over Freeman in view of Snyder (US 6,356,785). Neither Freeman nor Snyder teach that the magnitude at which to supply pacing stimuli can be based, at least in part, upon a physical parameter.

Snyder's teachings are directed generally to the prompting of a rescuer to intervene or take certain actions. Claim 9 recites "*automatically* adjusting the magnitude and pacing rate..." (emphasis added). . At column 25, lines 26-34, cited by the Examiner, Snyder does not teach automatic adjusting the pacing therapy based upon current patient status; instead, it describes prompting a rescuer to perform certain acts. Claim 10 has been amended to add the word "*automatically*" to describe the terminating of discharge of energy. In claim 26, the controller is configured to terminate the discharge of the energy device. Neither Snyder nor Freeman teaches automatically terminating pacing therapy or a device with a controller that will terminate pacing therapy based on an updated patient parameter.

With respect to claims 11-14, the Examiner admits that neither Freeman nor Snyder teach identification of no electrical capture, mechanical capture, failure in improvement of cardiac output or adequate spontaneous circulation. The Examiner has cited no references showing the claim limitations in these claims and simply dismisses them out-of-hand as "obvious design choice". To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art (see MPEP, 2143.03). Since the Examiner has not cited prior art showing these claim limitations, she has not made out a *prima facie* case for obviousness.

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With respect to claims 15, through 24, neither Freeman nor Snyder teach that the magnitude at which to supply pacing stimuli can be based, at least in part, upon a physical parameter. Likewise, the additional references cited against some of these claims (Brown and Sherman) likewise do not supply what is lacking in the Freeman reference.

For at least the reasons discussed above, the Examiner has failed to establish anticipation or *prima facie* obviousness of the claimed subject matter.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant believes that no additional fees are needed for processing of this Amendment. However, if any fees are due, please charge any such fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

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ECC Guidelines

Part 4: The Automated External Defibrillator

Key Link in the Chain of Survival

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► Major Guidelines Changes

Following are the major guidelines changes related to use of automated external defibrillators (AEDs) in basic life support:

1. Early defibrillation (shock delivery within 5 minutes of EMS call receipt) is a high-priority goal.
2. Healthcare providers with a duty to perform CPR should be trained, equipped, and authorized to perform defibrillation (Class IIa).
3. For in-hospital defibrillation: a. Early defibrillation capability, which is defined as having appropriate equipment and trained first responders, should be available throughout hospitals and affiliated outpatient facilities (Class IIa).
4. b. The goal of early defibrillation by first responders is a collapse-to-shock interval, when appropriate, of <3 minutes in all areas of the hospital and ambulatory care facilities (Class I).
5. c. Response time intervals for in-hospital resuscitation events are often inaccurate and must be corrected before documented times to defibrillation can be considered reliable (Class IIa).

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After the first shock, do not restart CPR. Some AED models require that the rescuer immediately press the ANALYZE button. In other models the AED will automatically begin rhythm analysis after shock delivery. If VF persists, the AED will indicate it, and the "shock indicated" and "charging" sequence will repeat for a second and, if needed, third shock. The AED is programmed to reanalyze the victim's rhythm and provide a shock as quickly as possible after each shock, to a total of 3 shocks. The purpose of this cluster or series of 3 shocks is to identify and treat a shockable rhythm as quickly as possible. Therefore, during the series of 3 shocks the rescuer should not interrupt or interfere with the rapid analysis and shock pattern. AEDs are programmed to pause after each group of 3 shocks to allow 1 minute for CPR. Therefore, after 3 shocks, check signs of circulation and prepare to provide chest compressions and continue compressions and ventilations for 1 minute (see below).

► Outcomes and Actions After Attempted Defibrillation

"Shock Indicated" Message: Recurrent VF
 If signs of circulation do not return after 3 shocks, rescuers without immediate ACLS backup should resume CPR for 60 seconds. After 60 seconds most devices will prompt a check for signs of circulation. If VF continues, deliver additional rounds of 3 "stacked" shocks after appropriate analysis. Provide sets of 3 stacked shocks followed by 1 minute of CPR until the AED gives a "no shock indicated" message or ACLS is available.

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Do not check for signs of circulation between stacked shocks, ie, after shocks 1 and 2, 4 and 5, 7 and 8, etc. Checking for signs of circulation between shocks will delay rapid identification and shocking of persistent VF. The rapid sequence of shocks has the additional advantage of modestly reducing transthoracic impedance; this reduction will increase the effective energy delivered.

"No Shock Indicated" Message

Signs of Circulation Absent

When the AED gives a "no shock indicated" message, check for signs of circulation, and if there are no signs of circulation, resume CPR. Three "no shock indicated" messages suggest that there is a low probability that the rhythm can be successfully defibrillated. Therefore, rhythm analysis should be repeated only after 1- to 2-minute intervals of CPR. CPR should then be discontinued during rhythm analysis. No one should touch the victim during analysis.

Signs of Circulation Present

If signs of circulation are present, check breathing. If the victim is not breathing, provide rescue breathing at a rate of 10 to 12 breaths per minute. If the victim is breathing adequately, place him or her in a recovery position. The AED should always be left attached. If VF recurs, most AEDs will prompt the rescuer to check for signs of circulation (or "check patient"). The device will then

(end of excerpt)